

## REMARKS

### A. Status of the Claims

Claims 1-33 have been canceled and claims 34-40 are currently pending in the case. Claim 37 has been amended herein.

### B. Rejections Under 35 U.S.C. § 112

The Action rejects claim 38 under 35 U.S.C. § 112, first paragraph, arguing that the application fails to enable treatment of the claimed group of reproductive, developmental, skin, bone, hepatic, hematopoietic or central nervous system disorders. In particular the Action argues that the effect of blocking inhibin/betaglycan could not have been predicted and that undue experimentation would be required to determine what effect inhibiting inhibin/betaglycan interaction would have in any particular disorder (*i.e.*, any particular cell type). Applicants respectfully traverse the rejection since the instant application teaches the effect of the inhibin/betaglycan complex on intracellular signaling in number of different cell types and thus it would be clear to a skilled artisan what the effect of inhibiting said interaction would be. Furthermore, the specification clearly teaches methods for accessing the effect of inhibiting inhibin/betaglycan complex formation in any given cell type. Thus, even if the skilled artisan wished to confirm the effect of inhibiting complex formation in a particular cell or tissue type it would be a matter of routine screening to do so.

In some embodiments, the instant specification teaches methods for inhibiting the formation of inhibin/betaglycan complexes with anti-betaglycan antibodies thereby altering signaling from the complex. The specification demonstrates that inhibin/betaglycan complexes mediate signaling in cells from a variety of tissues such as kidney cells (Example 5 and 6) and ovarian and corticotrope cells (Example 8). Still further studies described in example 7 demonstrate that betaglycan is expressed in a wide range of inhibin-responsive tissues indicating

that antibodies may be applied to these tissues to modulate complex formation and thereby intracellular signaling. Furthermore, the specification clearly demonstrates that anti-betaglycan antibodies may be used to modulate signaling from inhibin/betaglycan complexes, see example 9. Thus, the applicants have provided enabling description of methods for modulating inhibin/betaglycan signaling on a wide range of cells with anti-betaglycan antibodies. As the Action notes, a role of inhibin signaling in a wide variety of cell types and disorders was well known in the art at the time the application was filed. For example, as stated in the Action, it was known that inhibin signaling played a role in reproduction, skin and fibrotic disorders has been described by Ferguson *et al.* (GB2306481) and Woodruff (1998). The Action further notes the a number of other disorders such as bone disorders (*e.g.*, tooth development) and hepatic disorders (*e.g.*, hepatic cancer) involve inhibin signaling complexes. Thus, the references identified in the Action demonstrate that that the role of inhibin signaling in the indicated range of disorders was known at the time the application was filed. Hence, in view of the teachings of the specification, the skilled artisan would clearly be able to use the claimed methods to modulate inhibin/betaglycan complex formation in the indicated range of cell types for the purpose of modulating intracellular signaling thereby treating the indicated range of disorders.

The foregoing arguments notwithstanding, it would be a matter of routine screening for a skilled artisan to confirm whether an anti-betaglycan antibody may be used to modulate inhibin/betaglycan signaling in a particular tissue or cell type. In fact, the specification provides detailed description of an assay techniques that may be employed in such screening. For instance, example 3 teaches a simple transfection-reporter method that may be used to measure intracellular signaling mediated by inhibin/betaglycan complexes. Thus, a skilled artisan may use this simple assay to confirm whether inhibin/betaglycan signaling can be modulated in any

given cell type. Applicants assert that the experimentation described above and detailed in the specification would constitute no more than routine screening for a person of ordinary skill in the art and thus clearly would not require undue experimentation.

In further arguments the Action has rejected claim 37, as failing to further limit claim 36. In response, Applicants have amended claim 37 to be dependent on claim 35. Applicants assert that the claim now presented is a proper dependent claim and the removal of this rejection is respectfully requested.

**C. Non-statutory Double Patenting Rejection**

The Action has rejected claims 34-40 on the principle of non-statutory obviousness-type double patenting over claims 1-4 of U.S. Patent No. 6,692,744. Applicants, disagree with the rejection set forth in the Action but in the interest of expediting the prosecution of the application a terminal disclaimer has been submitted herewith.

**D. Conclusions**

Applicants believe that in view of the forgoing arguments and amendments the instant application is in condition for allowance and such favorable action is respectfully requested. The Examiner is invited to contact the undersigned agent at (512) 536-3167 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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